

MEDICARE COVERAGE SOUGHT FOR ALLO TRANSPLANTS FOR MDS

Allogeneic stem cell transplants for myelodysplastic syndrome (MDS) would be consistently eligible for Medicare and Medicaid reimbursement if the federal government accepts a formal request that has been submitted by ASBMT and the National Marrow Donor Program (NMDP), together with 10 other organizations.

"We believe that the body of evidence supports a coverage policy that ensures that Medicare beneficiaries diagnosed with MDS have access to allogeneic HCT," said a letter asking for a national coverage determination, submitted Sept. 21 to the Centers for Medicare and Medicaid Services (CMS).

Medicare patients age 65 and older represent 80% of the total population diagnosed with MDS in the United States. For some of these patients, allogeneic hematopoietic cell transplantation (HCT) is the only available curative therapy and the only treatment that can prevent certain death from the disease.

Inconsistent Coverage

Currently some Medicare regional contractors for Part A (hospital) and Part B (physician) services do reimburse for stem cell transplants for MDS, but coverage is inconsistent across the country. Each instance may require extensive justification of the efficacy of allogeneic transplants for MDS. Without an explicit and well-defined national policy, hospitals often are reluctant to extend HCT services to Medicare beneficiaries who would benefit. A national coverage determination would guarantee appropriate and timely access to curative treatment for MDS under the federal health programs.

After months of gathering evidence to document a request, ASBMT and NMDP met with CMS representatives in February for preliminary discussion

about applying for a national coverage determination. The outcome was encouraging enough to proceed with assembling a coalition of organizations to submit a formal request. Those joining in the petition are:

- AABB (formerly the American Association of Blood Banks)
- American Cancer Society
- American Cancer Society Cancer Action Network
- American Society for Hematology
- American Society of Clinical Oncology
- Aplastic Anemia and MDS International Foundation
- Blood & Marrow Transplant Information Network
- National Bone Marrow Transplant Link
- The Bone Marrow Foundation
- The Leukemia & Lymphoma Society

Several other organizations have indicated that they will support the request during an expected period for public comment.

Included in the documentation submitted to CMS was an evidence-base review of the scientific and medical literature published in February this year, part of the ongoing series of comprehensive reviews of indications for HCT that ASBMT has sponsored and NMDP has supported over the past 10 years. Each review is conducted by a multidisciplinary panel of experts.

Another important part of the documentation was a study conducted by the Center for International Blood and Marrow Transplant Research (CIBMTR) showing that outcomes for older adults undergoing allogeneic HCT for MDS are not significantly different than those of younger adults, even after adjusting for multiple risk factors. The analysis, presented last year at the American Society of Hematology annual meeting, revealed no statistically significant impact of age on transplant-related mortality, relapse, leukemia-free survival or overall

survival. The report has been submitted for publication.

"The study involved 551 MDS patients in the CIBMTR database who were transplanted from 1995 to 2005," said Claudio Anasetti, MD, ASBMT president. "The analysis concluded that age by itself should not be a limiting factor for proceeding with allogeneic HCT in older MDS patients."

Safety and Quality

According to Michael Boo, JD, the NMDP's chief strategy officer, another important element in the petition was to show a high degree of safety and quality for all allogeneic HCTs for MDS and an ability to track and analyze outcomes of care for Medicare and Medicaid patients.

"For safety and quality we referenced NMDP standards and the transplant provider and facility standards and accreditation of the Foundation for the Accreditation of Cellular Therapy (FACT)," Boo said. "For ongoing evaluation of outcomes, we offered the capabilities of the federally mandated data collection of the Stem Cell Therapeutics Outcomes Database (SCTOD), which is maintained by the CIBMTR."

MDS becomes more common as people age. In the United States, the overall incidence of MDS is estimated at 3.3 per 100,000, but the incidence in those over 70 is between 15 and 50 per 100,000, according to recently published epidemiological data.

CMS may seek additional information prior to a period for public comment. A decision on the request isn't expected until next year.

STRATEGIC PLANNING SURVEY REVEALS MEMBERS' PRIORITIES

Research, Reimbursement and Recruitment. The three words represent top priorities of ASBMT members and where they are looking to their society's leaders for effective programs.

More than 400 members responded to an online questionnaire about the society's programs and activities. The strong response – about a third of the membership – came when the Board of Directors in May requested information and opinions for the development of the society's next three-year strategic plan.

The survey asked members the open-end question "What do you think is the greatest challenge facing our field today?" The answers most frequently given fit into the following three categories:

- Basic and clinical research and particularly funding for research (29%)
- Reimbursement, costs and access to care (24%)
- Workforce shortage and recruitment of physicians and other clinical personnel (20%)

The responding members said that the greatest opportunities for the BMT field are in further improvement of therapies through continued research (46%) and an expansion of the field into other cellular therapies, gene therapy and regenerative medicine (36%).

"The opinions and advice of our members was immensely helpful when the officers and directors met to begin crafting a strategic plan for the next three years," said Claudio Anasetti, MD, president. "The priorities expressed in the survey helped guide the deliberations of our officers and directors.

"The large response from our members speaks to the special relationship so many have with the society, and it added to the importance of our planning for the next several years," he said.

Programs Rated

The survey respondents were given a list of ASBMT programs and activities and asked to indicate the importance of each. The two that were ranked most important were evidence-based reviews, (chosen as "very important" or "important" by 90% of respondents) and the development of clinical guidelines (chosen as "very important" or "important" by 88% of respondents).

Other programs, ranked in descending order of importance were:

- Accreditation of transplant programs (FACT)
- Guidelines for BMT training
- Web site (www.asbmt.org)
- Annual research training course for young clinicians
- Advocacy with health plans on reimbursement issues
- New investigator awards
- Legislative and regulatory relations
- BMT economic studies
- Travel grants to young investigators for annual meeting
- Membership directory
- Public awareness and education about BMT
- Monthly e-newsletter (ASBMT eNEWS)
- Contracting assistance with third-party payers
- Online CME courses and seminars
- Standardized RFI (Request for Information)
- Online job opportunities (job bank)
- CPT Code improvements

Overall, ASBMT programs and activities are ranked quite high. Even the program that scored lowest – CPT Code improvements – was rated "very important" or "important" by 62% of the respondents.

Annual Meeting

Nearly 60% of those participating in the survey said that they attended the BMT Tandem Meetings this past February in Tampa. Ninety-two percent rated the meetings as "very good" or "good."

Asked about the balance between clinical science and basic science, 85% percent said that the mix was about right. Ten percent said it skewed too much toward basic science, and 5% said it was too heavy in clinical science.

Among those who did not attend the meetings, the most frequent reasons were a personal schedule conflict (41%), not having the necessary travel budget (22%), or having to provide patient coverage so that others from their facility could attend (18%).

BBMT

The typical member spends between 30 and 60 minutes each month with *Biology or Blood and Marrow Transplantation* (32% of members), while some spend more than an hour (19% of members).

Asked to rate the journal on several attributes, the highest score was given to its impact on members of the BMT field. Other highly ranked attributes were:

- Physical quality (layout, typography, figures, use of color)
- Overall reputation of the journal
- Stature of editor/editorial board
- Balance between basic science and clinical research

Only *Blood* outscored BBMT on relevance to the hematopoietic stem cell transplant field. In terms of content quality, BBMT was ranked just behind *Blood*, *New England Journal of Medicine* and *Journal of Clinical Oncology*.